

REMARKS

The present invention is drawn to a method of treating or suppressing obesity in a subject in need thereof, comprising administering to the subject an effective amount of an anti-obesity agent which comprises either D-cysteinolic acid represented by Formula I in Claim 17 (Claims 17-20), sea lettuce or an extract therefrom (Claims 21-24); or an extract from sea lettuce obtained with water at a temperature of 50-70°C (Claims 25-28); or at least any one of D-cysteinolic acid, sea lettuce, and an extract thereof (Claim 30).

The rejection of Claims 17-28 and 30 under 35 U.S.C. § 102(b) as anticipated by JP2001-046051A (Hirayama et al), is respectfully traversed.

Hirayama et al discloses that D-cysteinolic acid is contained in sea lettuce and can be extracted using hot water. Hirayama et al further discloses that D-cysteinolic acid has utility both against thrombosis and as a cholesterol-reducing drug, which have already been acknowledged in the specification herein in the paragraph bridging pages 1 and 2.

The Examiner admits that suppression of obesity is not disclosed but finds that the reference inherently anticipates the claims "because both the reference and the claims are administering the same composition to the same patient" in that "[a]ny person has the potential to become obese."

In reply, based on the known utility for D-cysteinolic acid, one skilled in the art would use it to treat those subjects in need of anti-clotting or cholesterol-reducing. High cholesterol is not necessarily associated with obesity. Indeed, some subjects of normal weight have high cholesterol, and some obese subjects have normal cholesterol. The presently-recited method, on the other hand, is directed to subjects in need of an anti-obesity agent, and this is not anticipated by Hirayama et al. Compare *In re Shetty*, 566 F.2d 81, 195 USPQ 753 (CCPA 1977) (**copy enclosed**) (method of curbing appetite not inherent or obvious over method to combat microbial infestation in same subject, even if respective

obvious over method to combat microbial infestation in same subject, even if respective amounts correspond.)

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The rejections under 35 U.S.C. § 103(a) of Claims 17, 18, 20 and 30 as unpatentable over JP03118319A2 (Mimura et al) in view of U.S. 4,220,653 (Vivino), and of Claims 21, 22, 24-26, 28 and 30 as unpatentable over Mimura et al in view of Vivino, and further in view of Hirayama et al, are respectfully traversed.

Mimura et al discloses, as gastric juice-secretion inhibitors, derivatives of cysteinolic acid that includes even cysteinol itself. The full text of Mimura et al describes the pharmaceutical activity and mechanism for a particular compound disclosed in Mimura et al under a "Experimental Examples" section, i.e., [(R)-2-aminopropyl]disulfide (Me-SS). This compound has the formula  $\text{NH}_2\text{-CH}(\text{CH}_3)\text{-CH}_2\text{-S-S-CH}_2\text{-CH}(\text{CH}_3)\text{-NH}_2$ . This is the only compound for which pharmaceutical activity has been confirmed in Mimura et al. Cysteinolic acid includes a sulfonic acid group, whereas Me-SS includes a disulfide bond. These compounds are clearly different from each other. Moreover, the fact that Me-SS has a gastric juice secretion suppressing effect does not at all suggest that cysteinol itself has the same pharmaceutical effect. Nor does Mimura et al disclose or suggest that cysteinolic acid has an effect of treating or suppressing obesity.

The Examiner relies on Vivino as disclosing that gastric juice secretion inhibitors are used to treat obesity, relying on the disclosure therein at column 2, lines 7-24.

The Examiner relies on Hirayama et al as disclosing that D-cysteinolic acid is contained in sea lettuce and can be extracted using hot water.

The Examiner holds, in effect, that the above combination of prior art suggests that D-cysteinolic acid, or D-cysteinolic acid obtained from sea lettuce, is a gastric juice secretion inhibitor, and that a gastric juice secretion inhibitor is, in effect, an anti-obesity agent.

In response to the argument made in the last response that the presence of the sulfonic acid group in D-cysteinolic acid is believed to serve an important role, the Examiner finds that Applicants have not explained why it is important. However, in so finding, the Examiner does not respond to the above argument with regard to the difference between D-cysteinolic acid, and the disulfide compound of Mimura et al. Rather, the Examiner simply finds that these respective compounds are "structurally similar." There is no evidentiary basis for this finding. Thus, the Examiner has no rebuttal to Applicants' statement that presence of the sulfonic acid group in D-cysteinolic acid is believed to serve an important role. Even without this statement, the Examiner is not justified in relying on the disulfide compound of Mimura et al.

Regarding the action of gastric juice secretion inhibitors, Applicants previously argued that Vivino discloses that gastric juice secretion inhibitors act to reduce a feeling of hunger which overweight persons experience when they consume smaller meals than those to which they have been accustomed. In other words, gastric juice secretion inhibitors act to cause subjects to eat less food. This is different from suppressing or treating obesity. Indeed, based on the *in vivo* data in the specification demonstrating the effectiveness of the above-discussed active ingredients, the anti-obesity effect was not based on a suppression of appetite or a lesser consumption of food. The newly-submitted Hirayama Declaration supports this statement, i.e., in the experiments performed as described in Example 2 in the specification herein, all the tested groups, including the control group, ate the same amount of food.

In sum, the applied prior art does not conclusively show that D-cysteinolic acid is a gastric juice secretion inhibitor, but even if it did, Applicants have shown that there is no connection between gastric juice secretion inhibition and the presently-recited treating or suppressing obesity.

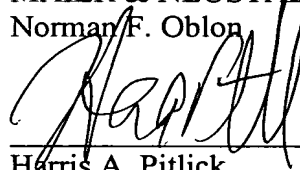
For all the above reasons, it is respectfully requested that the rejections over prior art be withdrawn.

All of the presently-pending claims in this application are believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Norman F. Oblon



---

Harris A. Pitlick

Registration No. 38,779

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 08/03)  
NFO/HAP/cja